REMARKS/ARGUMENTS

Claims numbered 1-6 and 8-9 were filed in this application. That is, there was no claim 7 filed in the case due to a typographical error in the Preliminary Amendment filed with the application.. Notwithstanding the above, however, the Office Action indicates that "claims 1-9 are pending" in the application and that claims 1-9 are rejected. In light of this situation, for purposes of clarification "claim 7" is indicated above as being "canceled" from the application.

Claims 1, 3 and 5 are amended herein to more clearly recite applicants' compositions and method. Furthermore, claims 8 and 9 are canceled (without prejudice or disclaimer), i.e., due to the amendments made as noted above to claims 1, 3 and 5. No new matter is added by any of the claim amendments and the entry of these amendments into the file of the application is, therefore, respectfully requested. Upon such entry, claims 1-6, as amended, will be pending in the application.

Claim Rejections Under 35 U.S.C. §112

Claim 3 is rejected under 35 U.S.C. §112, second paragraph, due to the inclusion therein of the phrase, "an effective amount of a P2X7" which, according to the Office Action, renders the claim indefinite.

In response to the rejection, applicants have amended the subject claim to delete the indicated phrase. This amendment is believed to overcome the rejection under §112, which should therefore be withdrawn.

Claim Rejections Under 35 U.S.C. §103

Claims "1-9" are rejected under 35 U.S.C. §103 as being allegedly unpatentable over Neely (WO 99/38532) and Smith et al., *The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial death*, Veterinary Immunology and Immunopathology, 78, 2001, pp. 249-262. The rejection is respectfully traversed.

The Neely reference discloses a method for inhibiting fibrosis and sclerosis in a subject with a fibrotic or sclerotic disorder by administering an amount of a P2X antagonist (see, e.g., p. 4, lines 14-16). The reference, in addition, describes sclerosis as constituting a loss of muscular

function due to an increase in fibrosis. As the Examiner has indicated in the Office Action, Neely does not disclose the use of o-ATP as a P2X antagonist.

The Smith et al. reference, in turn, discloses that P2X7 is an ionotropic channel regulated by ATP that plays an important role in a variety of immune responses (see p. 249, Introduction) and an important effector pathway of immune response (p. 260, first paragraph). The reference, in addition, mentions that o-ATP and KN-62 are antagonists of the purinergic receptors P2X7 (p. 260, first paragraph).

The Examiner takes the position, in light of the above, that it would have been obvious to one having an ordinary level of skill in this art to use o-ATP in the treatment of autoimmune diseases since o-ATP is an important effector pathway in the immune response described in Smith et al. while P2X antagonists are useful in the treatment of fibrosis/sclerosis such as has been described in Neely.

In response to the above-described 'obviousness' rejection, applicants have amended claims 1 and 5, and further amended claim 3 such that the pending claims are now all directed to compositions (and method of making the same) for the treatment of, specifically, multiple sclerosis, which includes a P2X7 purinergic receptor antagonist. Additionally, as indicated above, claims 8 and 9 are canceled without prejudice or disclaimer since their subject matter is now incorporated into their respective parent claims. For the reasons which follow, applicants respectfully submit that claims 1-6 in their present amended form are believed to be completely distinguishable over the combined disclosure of the Neely and Smith et al. references.

Applicants note for the Examiner's consideration that while the Neely reference does mention the use of P2X receptors for the treatment of, in general, fibrosis and sclerosis, and wherein it does mention treatment of, *inter alia*, certain autoimmune diseases (see, e.g., p. 7), there is no specific teaching or disclosure contained in the subject reference concerning the treatment of, in particular, multiple sclerosis (to which the claims are now all particularly directed).

Further to the above, it is also important to note that the Neely reference does not refer to the use of P2X7 antagonist, as in the case of the present claims. Instead, it refers to P2X receptors. The present claims are directed to the selection of a particular antagonist (P2X7) for treatment of a particular disease (multiple sclerosis). Such a selection is not anticipated by either Neely or Smith, et al.

Nor would the claimed compositions and/or method be obvious to one having an ordinary level of skill in this field over the combined disclosure of the two references, since the Neely reference is directed to the treatment of fibrosis, and the resultant sclerosis, from an inflammatory process by means of P2X antagonists. Multiple sclerosis is, however, a complex disease which not only has an inflammatory phase, but also a neurodegenerative phase. It would, thus, not be obvious to apply the teachings of the Neely reference for the treatment of, in particular, multiple sclerosis, with a reasonable expectation of success. Still further, it would not be obvious to use, specifically, the P2X7 antagonist for, in particular, the treatment of multiple sclerosis. The efficacy of the claimed compositions and method (i.e., as now recited in applicants' amended claims) used for the treatment of multiple sclerosis in mammals is demonstrated, e.g., in the Example at pp. 19-20 of the present specification) which details the course of treatment as well as the surprising and unexpected results obtained in a multiple sclerosis mice model. This, then, additionally supports the non-obviousness of applicants' claims.

For the reasons presented above, therefore, applicants respectfully submit that claims 1-6 in their amended form are not obvious over the combination of references cited in the Office Action. The Examiner is thus respectfully requested to reconsider and withdraw the rejection of applicants' claims under 35 U.S.C. §103.

Respectfully submitted,

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON November 25, 2009.

MAF:stb

Mark A. Farley
Registration No.: 33,170
OSTROLENK FABER LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700